



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Interacting with Industry Stakeholders at the EMA

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European Medicines Agency/IFAH-Europe Info Day 2016

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An agency of the European Union





# Agenda

1. Overview of context

2. Framework for interaction

Back-up slide



# Context

*The EMA has been interacting with industry stakeholders on various levels since its creation.*

*Points of interaction include:*

- *early innovation task force or SME office briefings;*
- *business pipeline meetings;*
- *direct contacts during regulatory procedures;*
- *consultation on guidelines;*
- *interaction during workshops/events;*
- *Etc.*

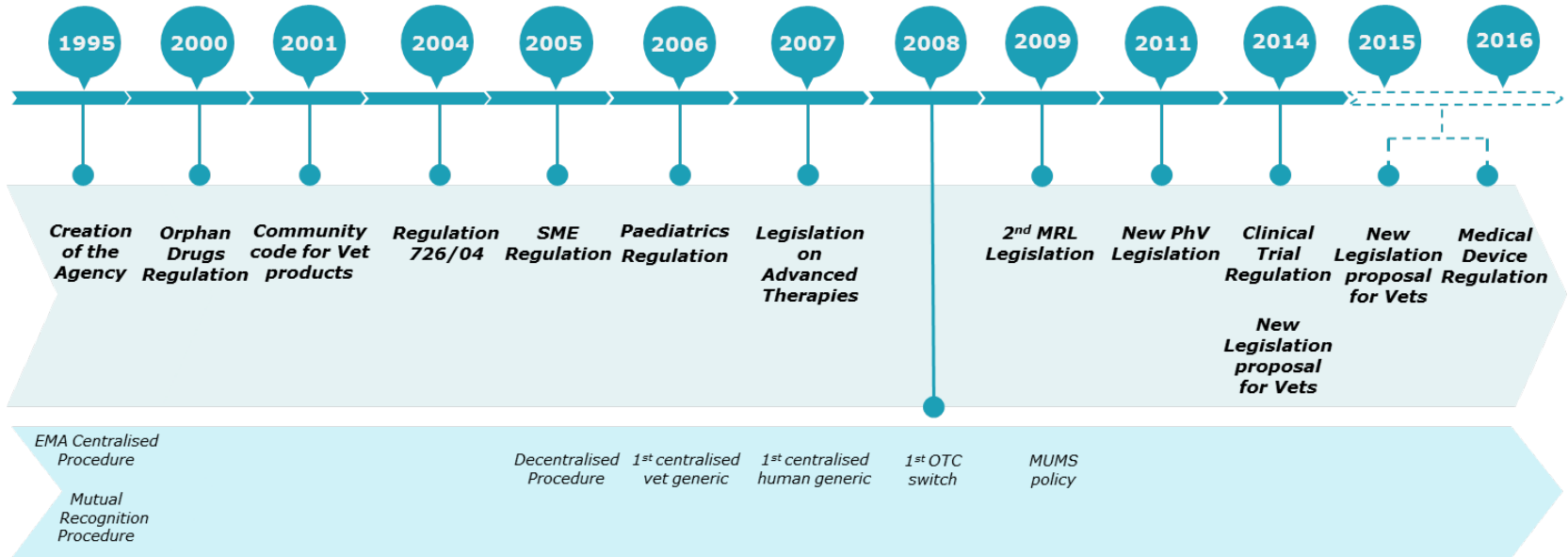
## **Key external stakeholder groups**

- *Patients*
- *Healthcare Professionals*
- ***Pharmaceutical Industry***
- *Academia*





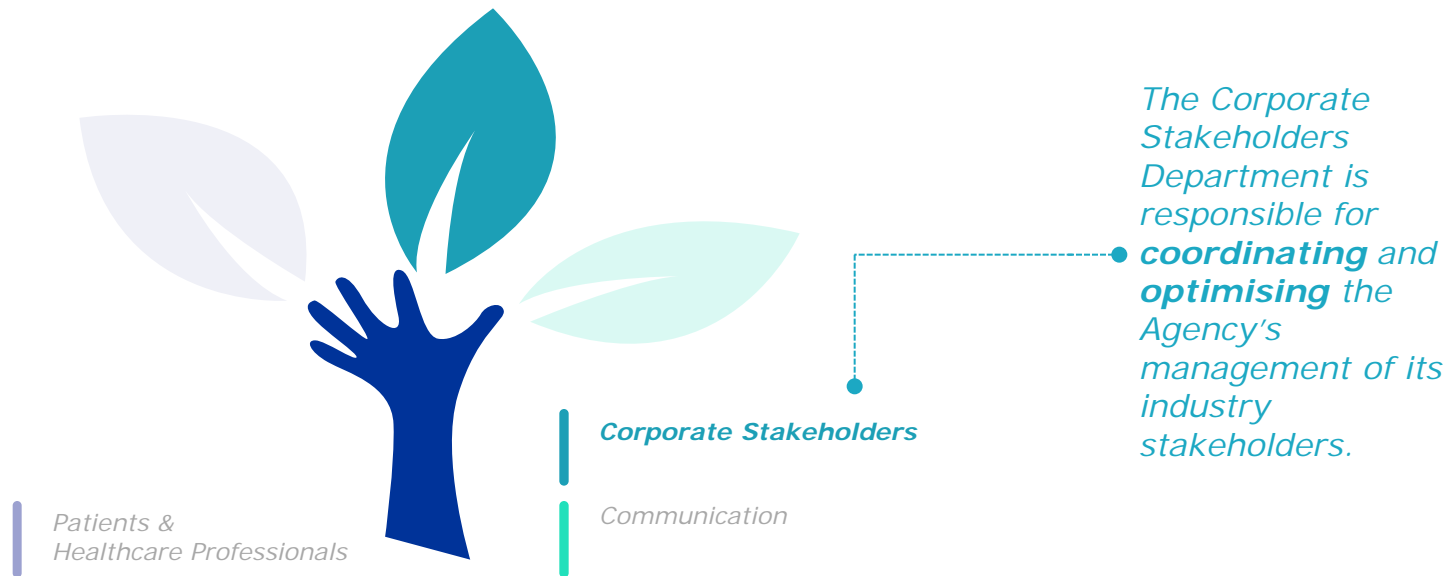
The Agency has grown in size and the scope & complexity of its responsibilities under EU legislation have increased.



*Need to further streamline the Agency's approach to stakeholder management.*



# Creation of the Corporate Stakeholders Department in the Stakeholder & Communication Division (q2 2014)



*Priority action 2014/15: Development of a framework for interaction with industry stakeholders.*



# Framework for interaction with industry stakeholders

## *Stakeholder mapping*



The framework will cover human & *veterinary* organisations.

Associations of professionals operating in or supporting the industry

Associations of service providers to the industry



Pharmaceutical industry trade associations.

Associations with multi-stakeholder membership including industry.

Organisations engaged early on in the innovation life-cycle from development



# • Framework for interaction with industry stakeholders

## *Objectives*



*To oversee and manage EMA's interaction with industry stakeholders.*

*Promote dialogue with industry stakeholders.*

*To increase clarity and consistency in collaboration and communication with external stakeholders.*

*Enrich the EMA's understanding of issues that are pertinent from the industry perspective.*

*Provide efficient, targeted and timely information, in a proactive manner;*

*Increase transparency of stakeholders engaging with the EMA and report on the interaction.*



# • Framework for interaction with industry stakeholders

## *Methods of interaction*

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### **INFORM**

→ to enable feedback e.g. news items, Q&As, information days;

### **CONSULT**

→ via written consultation e.g. guidelines development, public consultations on deliverables, focus groups;

### **CONSULT & INVOLVE**

→ based on direct interactions e.g. focus groups;

### **CO-OPERATE**

→ jointly engaging towards a common technical goal e.g. technical expert groups.



# Thank you for your attention

## Further information

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[Insert relevant information sources or contact details as applicable.]

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# Back-up slide: Eligibility criteria

Criteria to be fulfilled by industry stakeholder organisations involved in European Medicines Agency (EMA) activities.

## **Legitimacy**

*The organisation should have statutes registered as European umbrella organisations in one of the Member States of the EU/EEA, and be non-for-profit. These should be documented.*

## **Activities**

*The organisation should have, as part of its activities, a specific interest in medicinal products for human or veterinary use which should be documented (e.g. through a report or position papers in the area of medicinal products published on the organisation website).*

## **Entry in EU Transparency Register**

*The organisation should be registered in the European Commission EU Transparency registry.*

## **Representation**

*The organisation should be representative of all its Members/affiliations throughout the EU/EEA. It should not exclusively represent individual companies. Statements and opinions of the organisation should reflect the views and opinions of all its members and adequate consultation procedures should be in place.*

## **Mission / objectives**

*The organisation should have its mission/objectives clearly defined and a legitimate interest in the areas of work of the EMA stated when registering.*

## **Structure**

*The organisation should have governing bodies, which are elected by their members, where applicable.*